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OCT 2 2012

510(k) Summary

This 510(k) Summary for the Ulthera® System is submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(k) summary.

Applicant:	Ulthera, Inc.
Address:	2150 South Country Club Drive, Suite 21 Mesa, AZ 85210
Contact Person:	Suzon Lommel, VP of Regulatory & Quality Affairs
Telephone:	480-649-4069
Fax:	480-619-4071
Submission Date:	June 7, 2012
Device Trade Name:	Ulthera® System
Common Name:	Focused Ultrasound Stimulator Use System for Aesthetic Use
Classification:	Regulatory Class II
Classification Name:	Focused Ultrasound Stimulator Use System for Aesthetic Use
Product Code:	OHV
Legally Marketed	Name: Ulthera® System
Predicates:	510(k): #K072505
Applicable Guidance:	The *Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use* was developed in response to Ulthera's DeNovo submission and 510(k) clearance K0272505 for the Ulthera System.

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Device Description: The Ulthera® System consists of the following components:

- Ulthera® Control Unit
- Handpiece
- Transducers

Indications for Use: The Ulthera® System is indicated for use as a non-invasive dermatological aesthetic treatment to:

- lift the eyebrow (current cleared indication)
- lift lax submental (beneath the chin) and neck tissue (requested expanded indication)

Performance Data: To support the expanded indication, the Ulthera® System was evaluated in an open-label clinical trial investigating the clinical response following treatment with the Ulthera® System to achieve lifting of lax submental (beneath the chin) and neck tissue. Improvement was evaluated through quantitative assessment, qualitative assessment and patient satisfaction questionnaires. There were 51/70 patients that had an improvement of ≥20 mm^2 in lift, of these patients 84.3% were identified as showing improvement by masked evaluators. The adverse events resulting from treatment with the Ulthera® System during this study were mild, short-lived in duration, and resolved without incident. There were no serious adverse events (SAEs) or unanticipated adverse device effects (UADEs) related to treatment with the Ulthera® System.

Conclusion: Based on the design, materials, principle of operation, and intended use, the Ulthera® System is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ulthera, Incorporated
% Ms. Suzon Lommel
Vice President of Regulatory & Quality Affairs
2150 South Country Club Drive, Suite 21
Mesa, Arizona 85210

OCT 2 2012

Re: K121700
Trade/Device Name: Ulthera® System
Regulation Number: 21 CFR 878.4590
Regulation Name: Focused ultrasound stimulator system for aesthetic use
Regulatory Class: Class II
Product Code: OHV
Dated: August 1, 2012
Received: August 3, 2012

Dear Ms. Lommel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K121700

Device Name: Ulthera® System

Indications for Use:

The Ulthera® System is indicated for use as a non-invasive dermatological aesthetic treatment to:

- lift the eyebrow
- lift lax submental (beneath the chin) and neck tissue

Prescription Use ___x____ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121700